K 123234

JUL 5 2013

SECTION 05

510(k) Summary

DATE OF APPLICATION: 2013-06-21

APPLICANT: Ermis Medizintechnik
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1. Device Name

Ermis Medizintechnik Sterilization Container System consisting of:
1/1 Size, ¾ Size, ½ Size, Mini, Dental containers and Accessories

Trade Names: Sterilization Container Systems
Common Name: Sterilization Container
Classification Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories

2. Classification Product Code / Subsequent Code

Device	Medical Specialty	Review Panel	Product Code	Device Class	Regulation Number
Sterilization Wrap Containers, Trays, Cassettes & Other Accessories	Part 880	General Hospital	KCT	2	880.6850

3. Predicate Device

Ermis Medizintechnik Sterilization Container Systems are substantially equivalent to the following predicate devices, most recently cleared by the FDA:

Predicate Device	510(k) Number	510(k) Holder
Bahadir Sterilization Trays	K112190	Bahadir USA Corp.
SklarLite Rigid Sterilizatio0n Container Systems	K091720	Sklar Instruments

4. Description of the Device

Ermis Medizintechnik Sterilization Container Systems are reusable devices intended to allow sterilization of enclosed medical devices and to maintain sterility of the enclosed devices until used.

- Interchangeable components within the different sizes (Full size, ¾ size, ½ size, Wide Body, Dental, Mini, Flat).
- Containers are available with perforated and non-perforated bottom and perforated lids.
- Safety lids are available for 1/1 size, 3/4 size and 1/2 size. Safety lids protect filters during storage and/or transportation. The Lids are not intended to be used during sterilization.
- The lids are equipped with a silicone based gasket.
- All containers incorporate a filter system to be used with Ermis disposable paper filters without chemical indicator.
- To ensure effective sterilization and organization of sterilized goods, wire and screen baskets are available.

Available sizes:

1/1 size:
- 580 x 280 x 100 mm
- 580 x 280 x 135 mm
- 580 x 280 x 150 mm
- 580 x 280 x 200 mm
- 580 x 280 x 260 mm

3/4 size:
- 465 x 280 x 100 mm
- 465 x 280 x 135 mm
- 465 x 280 x 150 mm

1/2 size:
- 285 x 280 x 100 mm
- 285 x 280 x 135 mm
- 285 x 280 x 150 mm
- 285 x 280 x 200 mm
- 285 x 280 x 260 mm

Mini Container:
- 300 x 140 x 40 mm
- 300 x 140 x 70 mm
- 300 x 140 x 100 mm

Dental Container:
- 300 x 190 x 40 mm
- 300 x 190 x 65 mm
- 300 x 190 x 80 mm
- 300 x 190 x 100 mm
- 300 x 190 x 130 mm

5. Indications for Use

The ERMIS Sterilization Container System is intended to allow sterilization of the enclosed medical device and also maintain sterility during transport and storage for 30 days. The system consists of different models, such as 1/1 Size, ¾ Size, ½ size, mini and dental containers which may vary in size, perforations and color. All models are available with perforated lids and either perforated or non-perforated bottoms. To enable proper organization of sterilized goods, different wire- or sleeve baskets exactly adapted to the specific container dimensions are available. All models are intended to be used with Ermis single use paper filters.
The containers are reusable devices designed to be used with the following sterilization cycle parameters:

Pre Vacuum cycle:

4 minutes	3 minutes
132°C (270°F)	135°C (273°F)
Drying Time minimum 20 minutes	Drying Time minimum 16 minutes

Loading: Metal surgical instruments (scissors, clamps, forceps) and textiles

Maximum recommended loading:

Model	Dimension	Maximum Recommended Load in kg (lbs.) incl. Container weight	
		Instruments	Textiles
1/1 (Full-) Size Container	580x280x100	3.8 (8.3)	3 (6.6)
	580x280x135	5.2 (11.4)	4.1 (9.0)
	580x280x150	5.8 (12.7)	4.6 (10.1)
	580x280x200	7.7 (16.9)	6.1 (13.4)
	580x280x260	10 (22.0)	8 (17.6)
¾ Size Container	465x280x100	3.1 (6.8)	2.5 (5.5)
	465x280x135	4.2 (9.2)	3.3 (7.2)
	465x280x150	4.6 (10.1)	3.7 (8.1)
½ Size Container	285x280x100	1.9 (4.1)	1.5 (3.3)
	285x280x135	2.6 (5.7)	2 (4.4)
	285x280x150	2.8 (6.1)	2.2 (4.8)
	285x280x200	3.8 (8.3)	3 (6.6)
	285x280x260	4.9 (10.8)	3.9 (8.5)
Mini Container	300x140x40	0.4 (0.8)	0.3 (0.6)
	300x140x70	0.7 (1.5)	0.5 (1.1)
	300x140x100	1 (2.2)	0.8 (1.7)
Dental Container	310x190x40	0.6 (1.3)	0.5 (1.1)
	310x190x65	0.9 (1.9)	0.7 (1.5)
	310x190x80	1.2 (2.6)	0.9 (1.9)
	310x190x100	1.5 (3.3)	1.2 (2.6)
	310x190x130	1.8 (3.9)	1.4 (3.0)

6. Technological Characteristics

The Sterilization Containers are made of anodized aluminum alloy. The containers are constructed to be used in any conventional steam sterilizer and can be stacked safely on top of one another during sterilization without slipping out of place.
The ERMIS sterilization container systems allow a systematic organization of the entire instrument sterilization. Storage, transportation and disposal can be organized with the containers.

The filter retainer is locked by pressing down in center of the filter. The opening of the filter retainer succeeds by pressing the plate.

The performance of the subject container was validated for sterilant penetration/efficacy, maintenance of sterility, microbial barrier properties and use life. The container met acceptance criteria for all claimed tests.

6.1. Characteristics compared to the Predicate Device

	Ermis System	Bahadir System	Sklar System
PROPERTIES			
Indicated for use containing instruments to be sterilized in vacuum steam sterilizers	Yes	Yes	Yes
Reusable	Yes	Yes	Yes
Closed system	Yes	Yes	Yes
Sealed	Yes	Yes	Yes
DESIGN			
Incorporates Filter System to permit entry of sterilant	Yes	Yes	Yes
Incorporates filter system to prevent microbial migration during transport	Yes	Yes	Yes
Incorporates security lid to prevent damage / contamination of filter unit during transport	Yes	No	Yes
MATERIALS			
Container	Anodized Aluminium Alloy, Stainless Steel, Silicone	Aluminium Alloy, Stainless Steel, Silicone	Anodized Aluminium Alloy, Stainless Steel, Silicone
PERFORMANCE			
Load	Up to 22 lbs.	Up to 24.5 lbs.	Up to 25 lbs. for all container sizes
Lumened / cannulated instruments	No	Yes	Yes
Stainless steel medical devices	Yes	Yes	Yes

7. Testing

Testing in order to proof safety and effectiveness of Ermis Medizintechnik Sterilization Container Systems has been performed according to the requirements set out in ISO 10993-1.

7.1. Performance Testing

In order to demonstrate compliance to Safety and effectiveness requirements that apply to the device, performance testing has been conducted under consideration of the requirements for sterilization performance, reusability, maintenance of sterility and sterilization compatibility.

7.2. Biocompatibility

The devices subject to this submission consist of the same materials as the predicate devices and do not come into direct contact with the patient. Evaluation of biological risks resulting from devices or components with indirect patient contact has been performed in accordance to the requirements set out in ISO 10993-1.

8. Substantial Equivalence Summary / Conclusion

Based on available 510(k) information provided herein, Ermis Medizintechnik Sterilization Container Systems are considered substantial equivalent to the predicate devices in terms of indications for use, material, technology, design and performance specifications.

There are no differences between the devices which would raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 5, 2013

Ermis Medizintechnik
C/O Mr. Andre Weingerl
Regulatory Affairs Consultant
Medagent GmbH & Company KG
Griesweg 47
Muehlheim Baden-Wuerttmberg
GERMANY 78570

Re: K123234
Trade/Device Name: Sterilization Container System Consisting of: 1/1 Size, ¾ Size, ½ Size, Mini, Dental containers and Accessories
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: June 6, 2013
Received: June 10, 2013

Dear Mr. Weingerl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

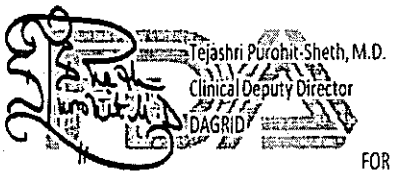
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



FOR

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K123234

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Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sreekanth Gutala -S
2013.07.02 14:27:40 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K123234

Device overview Ermis Sterilization Container System

Model	Dimension	Maximum Recommended Load in kg (lbs.) incl. container weight		Available configurations / Accessories
		Instruments	Textiles	
1/1 (Full-) Size Container	580x280x100	3.8 (8.3)	3 (6.6)	Perforated Lid; Perforated or non-perforated bottom; Optional safety-Lid for storage / transportation; Accessories: Stainless steel wire- or sleeve baskets; Available colours: Natural aluminium, anodized gold, red, blue, green, black
	580x280x135	5.2 (11.4)	4.1 (9.0)	
	580x280x150	5.8 (12.7)	4.6 (10.1)	
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